

US Serial No. 10/645248

Page 6 of 13

Remarks:

Regarding the rejection of claims 1-4, 12-15 and 17-21 under 35 USC 102(b) in view of US 4678658 to Casey et al. (hereinafter "Casey"):

The applicant traverses the rejection of the claims in view of the reference to Casey.

With regard to the Examiner's grounds of rejection under 35 USC §102(b), that statute holds in relevant part that a person shall be entitled to a patent unless "the invention was ... in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." Unpatentability based on "anticipation" requires that the invention is not in fact new. See *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995) ("lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee"). Anticipation requires that a single reference describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art. See, *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). It is the present applicants' position that this standard has not been met.

Regarding now the Casey reference, a skilled artisan reviewing that document would understand that the invention disclosed by Casey are to compositions are also distinguishable from the presently claimed compositions. More specifically, whereas the applicant's three essential constituents are: water, a selected alcohol from a defined group and a pH adjusting agent, the compositions according to Casey necessarily include: an

"..aliphatic alcohol with high volatility is used as the primary component by volume. The alcohol has bactericidal characteristics and allows for the rapid drying of the layer of disinfectant sprayed on the surface..." (Casey, column 2, lines 17 – 22);

The Casey compositions however also necessarily require a "germicide-surfactant" which is discussed in Casey as follows:

US Serial No. 10/645248
Page 7 of 13

"It is thought that the surfactant has two characteristics which contribute to this invention. Those being germicidal activity including effectiveness over a wide range of organisms including bacteria, virus and yeast and providing a reduction of the surface tension of the composition to achieve effective spread and distribution if the germicide on the surface is to be disinfected. Two different types of surfactants were tested separately and in combination for efficacy. It was found that both sodium dodecyl sulfonate and octyl phenoxy polyethoxyethanol are effective germicide-surfactants. There are other compounds which have the properties of germicide-surfactants, and this invention is not limited to those compounds shown in the examples." (Casey, col. 2, lines 37 – 50);

From the foregoing it is believed to be quite apparent that the Casey compositions do not anticipate or suggest the present applicant's compositions.

The Casey reference clearly teaches that the efficacy against microorganisms is achieved by the effect of both the large amount of alcohol necessarily present in conjunction with the "surfactant-detergent compounds" a mechanism which appears to be quite different from the "essential ingredients" which are essential to the present applicant's invention. There is no recitation in Casey with regards to any criticality respecting any specific combination of specific pH level and specific level of alcohol, nor for that matter, any specific and surprising inverse relationship between the pH level and the level of specific alcohol(s) present in the composition in order to achieve any kill against the polio virus. Furthermore, the Casey reference fails to disclose a system which is based only on the "essential constituents" which the present applicant teaches in their application. Casey can be contrasted in that while it does provide some degree of antimicrobial efficacy, the required constituents according to Casey are distinguishable from the applicant's "essential constituents" and thus the applicant's present claims should be considered as novel over the Casey reference.

US Serial No. 10/645248
Page 8 of 13

The Casey reference also fails to teach compositions which are based on anything other than 70%wt. isopropanol and 30% wt. water mixtures. (See Casey, col. 2, lines 26 – 29.) Thus Casey fails to suggest or demonstrate efficacy of his compositions at any lesser amount of alcohol being present.. That good overall efficacy can be attained at 70%wt. or greater amounts of alcohol being present is well known to the art; see the present application at page 1, lines 26 – 28 wherein this effect is discussed by the applicant as background to the present invention. Thus, Casey does not teach efficacy against poliovirus type 1 at anything but such high concentrations of alcohol which was known to the art.

The Casey reference also fails to teach any relationship between the amount of alcohol which may be present or the pH of the composition. Such is a dual failure as Casey fails to demonstrate any variability in the amount of isopropanol which may be used, and fails to demonstrate efficacy at compositions other than at a pH of 12.53. From Casey's Examples I, II and III it appears that all testing was done using an example composition which had a pH of 12.53 (see Casey, column 3, lines 57 – 58). Thus, no variability in the pH of the compositions and potential effect on microorganisms was disclosed either.

The applicant also points out that Casey's demonstrated efficacy is against a short list of microorganisms as outlined by Casey at col. 1, lines 53 – 58. As is known to a skilled practitioner in the arts, antimicrobial efficacy is not necessarily inherent or easily predictable against other types of microorganism, even of the same genus. Thus, it is also fair to say that Casey fails to demonstrate any efficacy of his microorganisms against those enumerated in the newly presented claim 22, namely *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Enterococcus hirae*, *Aspergillus niger*, *T. mentagrophytes*, Hepatitis A , Poliovirus Type 1, Coxsachievirus , Rotavirus, or Rhinovirus.

Accordingly, in view of the foregoing remarks, reconsideration of the propriety of the rejection under 35 USC 102(b) is requested, and it is further requested that the rejection be withdrawn.

US Serial No. 10/645248
Page 9 of 13

Regarding the rejection of claims 5-7, and 16 under 35 USC 103(a) over US 4678658 to Casey in view of EP 0099209 to Coates (hereinafter "Coates"):

The applicant respectfully traverses the rejection of claims 5-7 and 16 in view of the combined Casey and Coates references.

For the sake of brevity, the applicant herein repeats and incorporates by reference all of the foregoing remarks concerning the Casey reference as being equally applicable with regard to the instant grounds of rejection.

With respect to the Coates reference, Coates recites at page 2 -3:

"According to the present invention, an aqueous disinfectant solution comprises:
a) 60 to 80% w/w of a C₁ to C₄ alkanol;
b) a bisguanide antimicrobial agent; and
c) a quaternary ammonium antimicrobial agent, wherein the combined concentration of the antimicrobial agents in the solution is up to 2% w/v.

Preferably the combined concentration of the antimicrobial agents in the solution is up to 2% w/v."

Coates later recites at page 4:

"The composition may also include a chelating agent, such as ethylenediaminetetra-acetic acid (EDTA), which are known to render some microorganisms more susceptible to antimicrobial agents."

From the foregoing it is believed to be quite apparent that the Coates compositions do not anticipate or suggest the present applicant's compositions, nor would they render the currently claimed compositions obvious if considered in conjunction with the Casey

US Serial No. 10/645248

Page 10 of 13

reference. Coates clearly teaches that the efficacy against microorganisms is achieved by the combination of the bisguanide antimicrobial agent with the quaternary ammonium antimicrobial agent. There is no recitation in Coates respecting any criticality respecting any specific combination of specific pH level and specific level of alcohol in achieving any kill any microorganism, particularly polio virus and other microorganisms which the applicant now claims in newly presented claim 22. Although Coates suggests that EDTA may improve the efficacy of antimicrobial agents, when read in the context of the Coates specification, such would be limited to the combination of the bisguanide antimicrobial agent with the quaternary ammonium antimicrobial agents taught. In any case, again, nothing in Coates provides any teaching or exemplification of the criticality of any specific combinations of specific pH level and specific level of alcohol in achieving any kill any microorganism, particularly the polio virus. The compositions in the Coates are demonstrated only against *Pseudomonas aeruginosa*, *Staph. aureus*, *Escherichia coli*, and *Salmonella choleraeuis*.

The applicant respectfully reminds the Examiner that the Federal Circuit has established clear guidelines that the claimed invention must be viewed ‘as a whole’ in lodging and maintaining a rejection under 35 USC 103. In *Princeton Biochemicals Inc. v. Beckman Coulter Inc.*, 75 USPQ2d 1051 (CA FC 2005) the Court of Appeals for the Federal Circuit expounded that:

“[...] section 103 requires assessment of the invention as a whole. *Id.* This “as a whole” assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the prior art and combined them in the claimed manner. *Id.* In other words, section 103 requires some suggestion or motivation, before the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998) “

Additionally, with respect to rejections lodged under 35 USC 103(a), the Examiner is reminded that there must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to

US Serial No. 10/645248
Page 11 of 13

make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). “Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). With regard to such a suggestion the Courts have also clearly stated it is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to “[use] that which the inventor taught against its teacher.” *W.L. Gore*, 721 F.2d at 1553. Only by insisting upon this rigor can the court avoid entry into the “tempting but forbidden zone of hindsight,” *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873 [228 USPQ 90] (Fed. Cir. 1985). It is not believed that the Examiner’s current rejection under 35 USC 103(a) meets these requirements.

In brief, each of the mechanisms for the elimination of microorganisms recited in the Casey and Coates references are distinguishable from the specific pH level and specific level of alcohol taught by the present applicant’s specification with regard to antimicrobial efficacy. Casey teaches that its antimicrobial efficacy arises from its recited “surfactant-detergent compounds”, and that the role of pH is relevant only to ensuring the de-colorization of its pH sensitive dyestuff. Casey is wholly silent however as to any efficacy against the microorganisms recited in new claim 22, and absent such a teaching such efficacy cannot be presumed. The Coates compositions clearly define that a combination of a bisguanide antimicrobial agent with a quaternary ammonium antimicrobial agent provides its antimicrobial efficacy against several microorganisms. Coates is also silent however, as to any efficacy against the polio virus as well as the further specific microorganisms recited in new claim 22, and absent such a teaching such efficacy cannot be presumed. Any combination of the Coates and Casey references

US Serial No. 10/645248

Page 12 of 13

would require that the resultant compositions necessarily include Casey's essential recited "surfactant-detergent compounds" additionally in conjunction with Coates' essential combinations of a bisguanide antimicrobial agent with a quaternary ammonium antimicrobial agent provides its antimicrobial efficacy, which would result in an "antimicrobial cocktail" of sorts in order to provide antimicrobial efficacy against a limited number of microorganisms. Such however would not recognize or suggest any antimicrobial efficacy against each of *Salmonella choleraesuis*, *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Enterococcus hirae*, *Aspergillus niger*, *T. mentagrophytes*, Hepatitis A, Poliovirus Type 1, Coxsachievirus, Rotavirus, or Rhinovirus by the applicant's three essential constituents, viz., "system", whose necessary constituents include water, a alcohol constituent selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, n-butanol, benzyl alcohol, and mixtures thereof and a pH adjusting agent.

Accordingly, in view of the foregoing remarks, reconsideration of the propriety of the rejection under 35 USC 103(a) is requested, and it is further requested that the rejection be withdrawn.

Should the Examiner in charge of this application believe that telephonic communication with the undersigned would meaningfully advance the prosecution of this application, they are invited to call the undersigned at their earliest convenience.

PETITION FOR A ONE-MONTH EXTENSION OF TIME

The applicants respectfully petition for a one-month extension of time in order to permit for the timely entry of this response. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this petition.

The undersigned notes that this response is being filed on a Sunday, and prior to the first business day following the expiry of the one-month extended response due period which was a Saturday. Thus, a one-month extension of time and fee is believed to be proper.

US Serial No. 10/645248
Page 13 of 13

CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Respectfully Submitted;

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11 Feb. 2007

Date:

CERTIFICATION OF TELEFAX TRANSMISSION:

I hereby certify that this paper and all attachments thereto is being telefax transmitted to the US Patent and Trademark Office to telefax number: 571 273-8300 on the date shown below:

Andrew N. Parfomak

Andrew N. Parfomak

11 Feb 2007

Date:

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